



**PROPOSED RULE MAKING
(RCW 34.05.320)**

CR-102 (7/22/01)
**Do NOT use for expedited
rule making**

Agency: **State Board of Health**

- ☒ Preproposal Statement of Inquiry was filed as WSR 02-03-136; or
☐ Expedited Rule Making -- Proposed notice was filed as WSR _____ or
☐ Proposal is exempt under RCW 34.05.310(4).

- ☒ Original Notice
☐ Supplemental Notice to WSR _____
☐ Continuance of WSR _____

(a) Title of rule: **Chapter 246-650 Newborn Screening**

Purpose: **This chapter identifies the list of mandatory disorders for newborn screening conducted by the Department of Health. The current list of disorders includes PKU, congenital hypothyroidism, congenital adrenal hyperplasia and hemoglobinopathies such as sickle cell disease. The purpose of the screening is to identify disorders that if not detected can cause severe mental and physical defects or death.**

Other identifying information: **The proposed changes reflect the recommendations made by the Newborn Screening Advisory Committee. The legislature granted funding for the addition of the proposed disorders during the 2003 legislative session.**

(b) Statutory authority for adoption: **RCW 70.83, RCW 43.20**

Statute being implemented:

(c) Summary: **The proposed changes add five disorders to the list of mandatory disorders. The additional disorders are: biotinidase deficiency, galactosemia, homocystinuria, maple syrup urine disease, and medium chain acyl-coA dehydrogenase deficiency. In addition, the proposal sets out privacy and security requirements for the handling and storage of the dried blood spots that are used to identify the disorders listed in chapter 246-650 WAC.**

Reasons supporting proposal: **The disorders required to be screened for by these rules have not been updated since 1991. Medical and technological advances in recent years have made it possible to screen newborns for an increasing number of disorders. These disorders, if not detected early can cause severe mental and physical defects or death. The proposed privacy and security requirements, will allow the department to better assure parents and families of the security of this health information.**

(d) Name of Agency Personnel Responsible for:	Office Location	Telephone
1. Drafting..... Mike Glass	1610 NE 150th Shoreline, WA 98155-9701	206-361-2890
2. Implementation.... Mike Glass	1610 NE 150th Shoreline, WA 98155-9701	206-361-2890
3. Enforcement..... Mike Glass	1610 NE 150th Shoreline, WA 98155-9701	206-361-2890

(e) Name of proponent:
Washington State Board of Health and Washington State Department of Health

☐ Private
☐ Public
☒ Governmental

(f) Agency comments or recommendations, if any, as to statutory language, implementation, enforcement and fiscal matters:
none

(g) Is rule necessary because of:

Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	← \ ← ← If yes, you must attach a copy of the Federal Citation or court decision.
Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	
State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	

(h) HEARING LOCATION:

Submit written comments to:
Mike Glass
1610 NE 150th Shoreline, WA 98155-9701
or via the internet at:
<http://www3.doh.wa.gov/policyreview>
FAX (206) 361-4996 By (date) **October 10, 2003**

Date: **October 15, 2003** Time: _____

DATE OF INTENDED ADOPTION: **October 15, 2003**

Assistance for persons with disabilities:
Desiree Robinson by **October**, 2003

TDD (800) **833-6388** or (360) **236-4107**

CODE REVISER USE ONLY

NAME (TYPE OR PRINT)

Don Sloma

SIGNATURE		
TITLE Executive Director	DATE	

(COMPLETE REVERSE SIDE)

(j) Short explanation of rule, its purpose, and anticipated effects:

The proposed changes add five disorders to the list of mandatory disorders. The additional disorders are: biotinidase deficiency, galactosemia, homocystinuria, maple syrup urine disease, and medium chain acyl-coA dehydrogenase deficiency. The proposal also establishes privacy and security measures for the storage and retention of specimens. The department of health tests for these disorders using the blood specimen that is routinely collected on all newborn infants before discharge from the hospital. The current list of disorders includes PKU, congenital hypothyroidism, congenital adrenal hyperplasia and hemoglobinopathies such as sickle cell disease. Expanding the list of disorders will assure that infants with these disorders are diagnosed early enough to prevent severe mental and physical defects and/or unexpected death.

In addition, the proposal sets out privacy and security requirements for the handling and storage of the dried blood spots that are used to identify the disorders listed in chapter 246-650 WAC. As a result, the department will be better able to assure parents and families of the security of this health information.

Does proposal change existing rules? ☒ YES ☐ NO

If yes, describe changes:

WAC 246-650-001 Purpose: is expanded to reflect the addition of privacy provisions to the chapter.

WAC 246-650-010 Definitions: adds definitions for biotinidase deficiency, galactosemia, homocystinuria, maple syrup urine disease, medium chain acyl-coA dehydrogenase deficiency, and newborn screening specimen/information form.

WAC 246-650-020 Performance of Screening Tests incorporates references to the new section on specimen retention and security, and references to the additional screening requirements.

WAC 246-650-030 Implementation of Screening sets a January 2004 date to begin the new screening requirements.

WAC 246-650-040 Report to the Board includes minor editorial changes.

(k) Has a small business economic impact statement been prepared under chapter 19.85 RCW?

☐ Yes. Attach copy of small business economic impact statement.
A copy of the statement may be obtained by writing to:

Telephoning: ()
Faxing: ()

☒ No. Explain why no statement was prepared

RCW 19.85.030 requires agencies to prepare a small business economic impact statement if a proposed rule imposes more than minor costs on businesses within an industry. This proposal imposes no new costs on small businesses; for this reason, the agency did not complete a small business economic impact statement.

(I) Does RCW 34.05.328 apply to this rule adoption? ☒ Yes ☐ No

Please explain:

Theh proposed rule is significant under RCW 34.05.328(5)(c)(iii)(C)because it significantly amends policy and the Newborn screening program by adding to the list of mandatory disorders for newborn screening.